K090389

BESTGEN Bestgen Biotech Corp.
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茂晶生技股份有限公司
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JUL 14 2009

II. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

2.1. General Information Establishment

- Manufacturer: **BESTGEN Biotech Corp.**
- Address: 7F, No.186, Jian 1st Rd. Jhonghe City, Taipei County, 23511, Taiwan, ROC
- Owner Number: **9102780**
- Contact Person: Dr. Jen, Ke-Min E-mail: ceirs.jen@msa.hinet.net
  886-3-5208829 (Tel); 886-3-5209783 (Fax)
  Address: No.58, Fu Chiun Street, Hsin Chu City, 30067, Taiwan, ROC
- Date Prepared: May 10, 2008

Device

- **Proprietary Name:** AP-1000 Blood Glucose Monitoring System
- **Common Name:** Blood Glucose Monitoring System
- **Classification Name:** SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER, Class II
- **Product Code:** NBW

2.2. Safety and Effectiveness Information

- **Predicate Device:**
  Claim of Substantial Equivalence (SE) is made to EASY CHECK Blood Glucose Monitoring System **(K062538)**
- **Device Description:** Based on an electrochemical biosensor technology and the principle of capillary action, AP-1000 Blood Glucose Monitoring System only needs a small amount of blood. Capillary action at the end of the test strip draws the blood into the action chamber and your blood glucose result is precisely and displayed in 6 seconds.

- **Intended Use:**

The AP-1000 Blood Glucose Monitoring System (BGMS) is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000 Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. AP-1000 Blood Glucose Test Strips must be used with the AP-1000 Meter. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

The AP-1000 Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. AP-1000 Blood Glucose Test Strips must be used with the AP-1000 Blood Glucose Meter. Testing is done outside the body (*In Vitro* diagnostic use). They are indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

MAJOR Level I/Level II Control Solutions are for use with the AP-1000 meter and AP-1000 Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

- **Synopsis of Test Methods and Results**

Pre-clinical and clinical data are employed upon submission of this 510(K) premarket notification according to the *Guidance Document for In Vitro Diagnostic Test System; Guidance for Industry and FDA* document provided by CDRH/ FDA.

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- **Substantial Equivalence (SE)**

  A claim of substantial equivalence is made to EASY CHECK Blood Glucose Monitoring System **(K062538).** Both of them have the same working principle and technologies. The differences are test time, coding method, test range, sample volume, meter dimension, weight, HCT range, and memory data number. Besides, the subject device is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger but the predicate device can test whole blood from the finger, forearm and palm. Thus the differences are due to the feature design aspects, not relating to the safety or effectiveness aspects. They are substantially equivalent.

Dr. Jen, Ke-Min
official correspondent for
BESTGEN BIOTECH CORP.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Bestgen Biotech Corp.
c/o Dr. Ke-Min Jen
58 Fu Chuin Street
Hsin Chu City, China (Taiwan) 30067

JUL 14 2009

Re: k090389
Trade/Device Name: AP-1000 Blood Glucose Monitoring System
Regulation Number: 21 CFR § 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: June 14, 2009
Received: June 18, 2009

Dear Ke-Min Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K090389

Device Name: ***AP-1000 Blood Glucose Monitoring System***

Indication For Use:

The AP-1000 Blood Glucose Monitoring System (BGMS) is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000 Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. AP-1000 Blood Glucose Test Strips must be used with the AP-1000 Meter. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

The AP-1000 Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. AP-1000 Blood Glucose Test Strips must be used with the AP-1000 Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). They are indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

MAJOR Level I/Level II Control Solution are for use with the AP-1000 meter and AP-1000 Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use _____ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use √ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k090389